

REMARKS

In the Advisory Action, the Office comments that antibodies, for example, which might be the result of the immunological response to STEAP-2 protein, would not be useful as diagnostics or prognostic tools because of the presence of this protein both in normal and malignant prostate, and concludes, on this basis, that antibodies to STEAP-2 would have not utility. However, this position fails to take account of the usefulness of these antibodies in ascertaining whether or not a particular malignant tissue does or does not express STEAP-2 protein. In the event that STEAP-2 protein is targeted by whatever therapy might be devised -- *e.g.*, perhaps itself an antibody to STEAP-2 or a small molecule pharmaceutical that targets this protein, it would be necessary to know whether the malignant tissue actually contains this as a target.

As is pointed out in the specification on page 45, line 30-46, line 11, STEAP-2 is expressed in some but not all, malignant cell lines and implants. This is verified in figure 16, referred to in this section of the specification, where it is clear that expression is present in some, but not all pancreatic cancers (lanes 22 and 23 as compared to lanes 20 and 21), in some but not all colon cancers (lanes 27 and 29 as compared to lanes 24-26 and 28), in some but not all cervical and ovarian cancers (lanes 42 and 44 as compared to lanes 40-41 and 43). In a manner analogous to, for example, the targeting of Her2, a successful current treatment for breast cancer, it is necessary to ascertain the presence of the target protein in order to determine whether treatment targeting this protein is worthwhile.

In addition, the presence of STEAP-2 in normal prostate is not a barrier to targeting this protein for treatment for two reasons. First, if a tumor is not resident in the prostate, the treatment may be administered directly to the tumor, thus avoiding the prostate altogether. More importantly, even if administration is systemic, loss of the prostate is an acceptable outcome; indeed, treating prostate cancer by targeting the normal prostate as well as the tumor has been suggested and is the subject of US Patent No. 5,925,362, wherein an immune response to the prostate itself is elicited by administration of prostate specific antigen *per se*. Accordingly, the presently pending claims which are directed to the specific protein disclosed as STEAP-2 and to

compositions which elicit an immunological response to this protein are directed to an invention which complies with the statute and is clearly characterized by a utility which is specific, substantive, and entirely credible.

Formal Matters

Finally, to attend to a formal matter, I hereby certify as applicant's undersigned attorney, that the deposit set forth as ATCC Deposit No. PTA-311 was made pursuant to the Budapest Treaty and all restrictions imposed by the depositor on availability to the public of this deposit will be irrevocably removed as of the issue date of the above identified patent application as a patent. The deposit will be replaced if viable samples cannot be dispensed by the depository. All of the requirements of the Budapest Treaty will be adhered to.

In light of the foregoing, it is believed that the Office should find claims 1 and 44-48 in a position for allowance and passage of these claims to issue is respectfully requested.

If outstanding issues remain which the Examiner believes can be resolved by a telephone discussion, a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 511582001620.

Dated: October 2, 2002

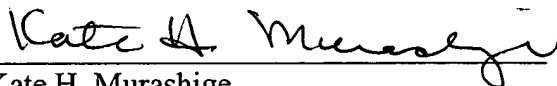
Respectfully submitted,
By: 
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EXHIBIT A. - VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend as follows:

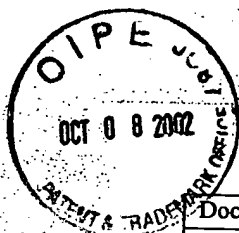
45. (Amended) A composition for inducing an immunological response [which cancer expresses a STEAP-2 protein,] said composition comprising a STEAP-2 protein according to claim 1 and a physiologically acceptable carrier.

47. (Amended) A composition for inducing an immunological response [which cancer expresses a STEAP-2 protein,] said composition comprising a STEAP-2 protein according to claim 44 and a physiologically acceptable carrier.

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Docket No.: 511582800000	Atty: Kate H. Murashige NBZ
Serial No.: See Attached Appendix	Filing Date: See Attached Appendix
Title: N/A	
Date of Mailing: February 11, 2002 via First Class Mail	

Papers enclosed herewith:

1. Transmittal Form (1 page)
2. Revocation of Prior Power of Attorney and Power of Attorney By Assignee (3 pages)
3. Appendix A (3 pages)
4. Return Postcard

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WILL ACKNOWLEDGE RECEIPT VIA FIRST CLASS MAIL OF THE ABOVE DOCUMENTS

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